



MAR 19 2002

George W. Johnston  
HLR Technology Corporation  
Patent Law Department  
340 Kingsland Street  
Nutley NJ 07110

Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,598,089

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,598,089, which claims the human drug product XENICAL (orlistat), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 5 years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 5 years.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of May 15, 2001 (66 Fed. Reg. 26866). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (3,091) + 878 \\ &= 2424 \text{ days (6.6 years)}\end{aligned}$$

Since the regulatory review period began June 12, 1988, after the patent issue date (July 1, 1986), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation, however, because the patent was issued after the date of enactment (September 24, 1984) of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,598,089
Granted:	July 1, 1986
Original Expiration Date <sup>1</sup> :	June 18, 2004

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<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).

Applicant: Paul Hadvary, et al.  
Owner of Record: HLR Technology Corporation  
Title: LEUCINE DERIVATIVES  
Classification: 514/449  
Product Trade Name: XENICAL (orlistat)  
Term Extended: 5 years  
Expiration Date of Extension: June 18, 2009

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents  
Box Patent Ext.  
Washington, D.C. 20231  
By FAX: (703) 872-9411  
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

  
Karin Tyson  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: David T. Read  
Acting Director Health Assessment Policy Staff, CDER  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852  
RE: XENICAL (orlistat)  
FDA Docket No.: 00E-1413